UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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U.S. SMOKELESS TOBACCO MANUFACTURING COMPANY, LLC and U.S. SMOKELESS TOBACCO BRANDS, INC.,

Plaintiffs,

- against -

CITY OF NEW YORK,

Defendant.

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09 Civ. 10511 (CM)

MEMORANDUM DECISION AND ORDER DENYING PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

McMahon, J.:

INTRODUCTION

Plaintiffs, manufacturers and distributors of smokeless tobacco, commenced this action on December 28,2009, challenging a recently enacted New York City law restricting the sale of flavored tobacco. Plaintiffs argue that New York's law is preempted by the federal Family Smoking Prevention and Tobacco Control Act ("FSPTCA") and violates the Commerce Clause and Due Process Clause of the Fourteenth Amendment of the United States Constitution.

Plaintiffs filed the motion for a preliminary injunction on January 26, 2010, on the sole ground that the city law is preempted by the FSPTCA. For the reasons set forth below, plaintiffs' motion for a preliminary injunction is denied.

CONSTITUTIONAL STANDARD

I. The Supremacy Clause

The "Constitution establishes a system of dual sovereignty between the States and the Federal Government," in order to "reduce the risk of tyranny and abuse from either front," Gregory v. Ashcroft, 501 U.S. 452,457 (1991). This balance of power translates into sovereignty for the states that is "concurrent with that of the Federal Government, subject only to limitations imposed by the Supremacy Clause." Tafflin v. Levitt, 493 U.S. 455,458 (1990).

The Supremacy Clause, Article VI, Clause 2 of the Constitution, provides that the laws of the United States "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any state to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. As the Supreme Court has explained, this clause represents an "extraordinary" grant of power, and gives the Federal Government "a decided advantage" in the dynamic between state and federal sovereigns. Gregory, 501 U.S. at 460.

However, the power vested in the Federal Government is not limitless. "The supremacy of the laws is attached to those only, which are made in pursuance of the constitution." 3 J. Story, Commentaries on the Constitution of the United States § 1831, at 694 (1833). Actions of the Federal Government "which are not pursuant to its constitutional powers, but which are invasions of the residuary authorities of the smaller societies," are not "the supreme law of the land. They will be merely acts of usurpation, and will deserve to be treated as such." Id. The Constitution confers upon Congress "not all governmental powers, but only discrete, enumerated ones," Printz v. United States, 521 U.S. 898, 919 (1997), and the Tenth Amendment reserves to the states, "[t]he powers

not delegated to the United States by the Constitution, nor prohibited by it." U.S. Const. amend. X. Put otherwise, as the Framers observed, the Constitution by design conveys "few and defined" powers to the Federal Government, while designating "numerous and indefinite" powers to the states. The Federalist No. 45, at 237-38 (James Madison) (M. Beloff ed., 2d ed. 1987).

"The regulation of health and safety matters is primarily, and historically, a matter of local concern," and therefore among those powers reserved to the states. Hillsborough County, Fla. v. Automated Med. Labs.. Inc., 471 U.S. 707, 719 (1985). Throughout history, the "[s]tates traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 756 (1985) (internal quotations omitted), overruled in part on other grounds by Kentucky Ass'n of Health Plans. Inc. v. Miller, 538 U.S. 329 (2003).

11. Preemption

Preemption is the vehicle used to operationalize Congress' grant of power under the Supremacy Clause. It applies with equal force to federal regulations promulgated by agencies cloaked with authority by Congress as to statutes directly by the legislature, including the imposition of damages under state law. Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 152-53 (1982); Geier v. Am. Honda Motor Co.. Inc., 529 U.S. 861 (2000); Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co., 450 U.S. 311 (1981) (same).

Every instance of preemption falls into one of two overarching categories: express or implied. Express preemption involves an express statement by Congress that prohibits

state and local governments from enacting laws in a specific area. As the Supreme Court has observed, "when Congress has made its intent known through explicit statutory language, the courts' task is an easy one." English v. Gen. Electric Co., 496 U.S. 72, 79 (1990). For example, in 1976, Congress amended the Federal Food, Drug, and Cosmetic Act ("FDCA") to add an express preemption provision (codified at 21 U.S.C. § 360k(a)). Section 360k(a) prohibits states from regulating medical devices, stating that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> **(2)** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a); see also Wveth v. Levine, 129 S. Ct. 1187, 1196 (2009) (discussing preemption under the FDCA).

While section 360k(a) is very broad, Congress will sometimes narrow the scope of an express preemption provision by carving out particular areas for state and local regulation. For example, in addition to preempting state regulation of medical devices under section 360k(a), the FDCA expressly preempts state requirements concerning over-the-counter medications and cosmetics (codified at 21 U.S.C. § 379r(e)). However, the FDCA preserves state product liability actions relating to those medications and cosmetics. See Wveth, 129 S. Ct. at 1200 n.8 (citing 21 U.S.C. §§ 379r(e), 379s(d) ("Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.")). This type of

carve out is called a "saving clause," because it saves certain powers of the states. See id. at 1196.

By contrast, implied preemption, which is also referred to as "conflict preemption," occurs in one of two circumstances-either "where it is impossible for a private party to comply with both state and federal law" or where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 372-73 (2000) (internal quotations omitted). Under the "purposes and objectives" inquiry, the critical question is not whether the state and federal governments share a common goal, but rather what effect the state law has on the federal statutory scheme—whether the state law interferes with a method the federal law uses to promotes its goal. Int'l Paper Co. v. Ouellette, 479 U.S. 481,494 (1987). The fact that state laws "impose liability over and above that authorized by federal law," without more, does not automatically mean that the state laws are preempted. California v. ARC America Corp., 490 U.S. 93, 105 (1989) (citing Silkwood v. Kerr-McGee Corp., 464 U.S. 238,257-58 (1984); California v. Zook, 336 U.S. 725,736 (1949)).

One of the most oft-cited examples of the so-called "purposes and objectives preemption" is Geier v. Honda Am. Motor Co., Inc., 529 U.S. 861 (2000). In that case, the Supreme Court applied the doctrine to the National Traffic and Motor Vehicle Safety Act of 1966, holding that certain state common law tort actions were preempted by the federal law because the state actions were an "obstacle" frustrating congressional intent. Id. at 886. The Court explained that the state actions frustrated congressional intent because while the federal law allowed car manufacturers to choose between a range of

options when equipping their vehicles with passive restraints (e.g., automatic belts or airbags), certain state law tort actions effectively eliminated that choice (part of the purpose of the law) by always requiring the installation of airbags. Id. at 881-82.

The most far-reaching form of conflict pre-emption is "field preemption." See English, 496 U.S. at 79-80 n.5 (field preemption can be considered a form of conflict preemption).[1] Field preemption is inferred in cases where federal law is so pervasive that it leaves "no room for supplementary state regulation" — where the federal law has fully occupied the field of regulation. Hillsborough County, Fla., 471 U.S. at 713 (internal quotations omitted); see also Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 604-05 (1991) (citing cases); English, 496 U.S. at 79 (citing cases); Rice v. Santa Fe Elevator Corp., 331 U.S. 218,230 (1947) (citing cases).

Neither the presence of an express preemption provision nor a saving clause will "foreclose (through negative implication) 'any possibility of implied [conflict] preemption.'" Geier, 529 U.S. at 869 (citations omitted, alterations in original). Rather, the presence of an express preemption clause means only that a court need not go "beyond that language to determine [in the first instance] whether Congress intended the [federal statute] to pre-empt at least ***some*** state law." Medtronic v. Lohr, 518 U.S. 470, 484 (1996) (emphasis added). However, a court interpreting an express preemption clause must go farther and analyze the scope or "domain" preempted by the statutory language. Id.

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[1] The Court recognizes, of course, that field preemption may also be exercised expressly, 1 L. Tribe, American Constitutional Law 1177 (3d ed. 2000); however, since the intricacies of the doctrine come into play only when field preemption is inferred, the Court subsumes the doctrine under the rubric of implied conflict preemption.

For example, the law at issue in Geier expressly preempted "any safety standard'—in that case, a standard relating to passive restraints—that was not "identical to a federal safety standard applicable to the same aspect of performance." Id. at **865.** It also contained a saving clause, providing that "compliance with a federal safety standard does not exempt any person from liability under the common law," which the state argued excepted its common law from preemption even though the common law effectively raised the federal safety standard by requiring manufacturers to install airbags in order to avoid tort liability. Id. at **868** (citation omitted). The Supreme Court explained that while the plain language of the saving clause could be read broadly as always permitting liability under a state's common law--even in the presence of a direct conflict with the federal statute—such an interpretation was at odds with Congressional intent. Id. at **869-70.** Thus, the Geier Court applied the doctrine of implied preemption and interpreted the saving clause narrowly, preempting only those state law actions that directly conflicted with the federal statute. Id. at 869-74.

Where, as in Geier, a court must interpret the scope of a preemption clause, two basic principles inform the court's analysis. First, because the states are independent sovereigns, it has long been presumed that "Congress does not cavalierly preempt state law." Lohr, **518** U.S. at **485** (state law causes of action). Thus, in all preemption cases, and especially those in which Congress has 'legislated . . . in a field in which the States have traditionally occupied,' courts must 'start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.' Id. (citations omitted). Indeed, in such situations, preemption is "ordinarily not to be implied absent an 'actual conflict.'"

English, 496 U.S. at 90 (citations omitted). Thus, the Supreme Court instructs that even where the text of a preemption clause is susceptible of more than one plausible reading, absent a conflict, courts should "accept the reading that disfavors pre-emption." Bates v. Dow Amosciences LLC, 544 U.S. 431,449 (2005).

Second, "'the purpose of Congress is the ultimate touchstone' in every preemption case." Lohr, 518 U.S. at 485. Therefore, "any understanding of the scope of a preemption statute must rest primarily on 'a fair understanding of ***congressional purpose.***"' Id. at 485-86 (citations omitted, emphasis in original). While Congressional intent is divined primarily "from the language of the preemption statute and the surrounding 'statutory framework,'" courts should also analyze the "structure and purpose of the statute as a whole." Id. at 486. However, the Supreme Court has instructed that "congressional silence lacks persuasive significance," Brown v. Gardner, 513 U.S. 115, 121 (1994) (internal quotation marks omitted)), and "matters left unaddressed in [a comprehensive and detailed federal] scheme" are presumed to have been left "to the disposition provided by state law," O'Melveny & Myers v. FDIC, 512 U.S. 79, 85 (1994). Thus, the Supreme Court's "preemption jurisprudence" "explicitly rejects the notion that mere congressional silence on a particular issue may be read as pre-empting state law." Camps Newfound/Owatonna, Inc. v. Town of Harrison, 520 U.S. 564, 616 (1997) (Thomas, J., Scalia, J., Rehnquist, C.J., dissenting) (citing Cal. Div. of Labor Standards Enforcement v. Dillingham Constr. N. A., Inc., 519 U.S. 316,325 (1997); Jones v. Rath Packing Co., 430 U.S. 519 (1977); Rice v. Santa Fe Elevator Corp., 331 U.S. 218 (1947)).

THE FEDERAL AND CITY LAWS

I. The Family Smoking Prevention and Tobacco Control Act

Against this constitutional backdrop, the Court turns to the provisions of the Family Smoking Prevention and Tobacco Control Act (the "FSPTCA" or the "Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), at issue in this case.

Enacted on June 22,2009, the purpose of the bill was "to amend the Federal Food, Drug, and Cosmetic Act ("FDCA") to grant the Food and Drug Administration (the "FDA") the authority to regulate tobacco products," H.R. Rep. No. 111-58, pt. 1, at 2 (2009) (the "FSPTCA Report"). The FSPTCA responds, at least in part, to holdings in two Supreme Court decisions: FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000), in which the Court held that the FDA lacked such authority under the FDCA, see 155 Cong. Rec. H6630-01, H6652, 2009 WL 1643915 (daily ed. June 12,2009) (statement of Rep. Waxman), and Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001), in which the Court held, inter alia, that the Federal Cigarette Labeling and Advertising Act ("FCLAA") preempted a state law regulating outdoor cigarette advertising aimed at reducing tobacco consumption by minors, see Commonwealth Brands. Inc. v. United States, No. 09 Civ. 117,2010 WL 65013, at *I (W.D. Ky. Jan. 15,2010).

A. Tobacco Products and Standards

The FSPTCA defines a "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)," provided that such product is not "an article that is a drug under [21 U.S.C. § 321](g)(1), a device under [21

U.S.C. § 321](h), or a combination product described in [21 U.S.C. § 353](g)." 21 U.S.C. § 321(rr)(1)-(2).

With respect to such products, the FSPTCA gives the FDA "the authority to regulate the sale, distribution, advertising, promotion and use of tobacco products if such actions would be in the interest of the public health," FSPTCA Report at 26, but prohibits the FDA from "banning a class of nicotine products, such as all cigarettes, or reducing the nicotine level [of such products] to zero." Id. at 2. The Act also "requires the [FDA] to establish tobacco product standards to protect the public health." Id.

The Act explains what is meant by "tobacco product standards," stating that regulation thereunder:

> (A) shall include provisions that are appropriate for the protection of the public health, including provisions, where appropriate—
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> (i) for nicotine yields of the product;
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> (ii) for the reduction or elimination of other constituents, including smoke constituents, or harmful components of the product; or
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> (iii) relating to any other requirement under subparagraph (B);
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> (B) shall, where appropriate for the protection of public health, include—
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> (i) provisions respecting the construction, components, ingredients, additives, constituents, including smoke constituents, and properties of the tobacco product;
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> (ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the tobacco product;
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> (iii) provisions for the measurement of the tobacco product characteristics of the tobacco product;
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> (iv) provisions requiring that the results of each or of certain of the tests of the tobacco product required to be made under clause (ii)

show that the tobacco product is in conformity with the portions of the standard for which the test or tests were required; and

(v) ***a provision requiring the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under [Section 906(d)]***;

(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper use of the tobacco product; and

(D) shall require tobacco products containing foreign-grown tobacco to meet the same standards applicable to tobacco products containing domestically grown tobacco.

21 U.S.C. § 387g(a)(4) (emphasis added). The italicized portion of the tobacco product standards provision, subsection B(v), is the only part of the tobacco product standards provision that authorizes the FDA to regulate sales of tobacco products.

Section 906(d), referenced ***supra*** in subsection (B)(v) of the tobacco product standards, gives the FDA authority to promulgate regulations restricting the sale of tobacco products, provided the agency first determines that such regulation would be in the "public interest." Section 906(d) makes clear that, while the agency "may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product," 21 U.S.C. § 387f(d)(1), the FDA may not "prohibit the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets," 21 U.S.C. § 387f(d)(3)(A). See FSPTCA Report at 37. The term "retailer" is defined in the statute as "any person, government, or entity who sells tobacco products to individuals for personal consumption, or who operates a facility where self-service displays of tobacco products are permitted." 21 U.S.C. § 387(14).

Section 906(d) also "requires the [FDA through the Secretary of Health and Human Services] . . . to regulate the sale, distribution, promotion, and marketing of tobacco products that are sold through means other than a direct, face-to-face exchange." FSPTCA Report at 37. This provision appears to have been designed primarily to allow the FDA to regulate internet sales of cigarettes.

Although the Act applies broadly to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," 21 U.S.C. § 387a(b), not all of the "tobacco product standards" promulgated by the Act apply to every type of tobacco product. For example, Section 907 sets forth a "tobacco product standard" in the form of a "Special Rule for Cigarettes" that prohibits the use in cigarettes — and only in cigarettes — of "characterizing flavors" other than tobacco or menthol, stating that:

> a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.

21 U.S.C. § 387g.

The rule was enacted following a finding that the ban on flavored cigarettes would not lead to "negative public health effects." FSPTCA Report at 38. Specifically, Congress found that flavored cigarettes, unlike regular and menthol cigarettes, are not "used regularly by a large number of addicted adult smokers," but tend to be used "occasionally, either by regular users of other products, by individuals who are experimenting with tobacco use, or by those who smoke only in certain social settings." Id. Therefore, a ban on these products would "not result in a large number of heavily addicted smokers facing the sudden withdrawal of the products to which they are

addicted, with unknown consequences for the health of the individual users or the overall population." Id.

The Act contains no similar limitation on flavored smokeless tobacco—a "tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity," 21 U.S.C. § 387(18). But the Act does contain some regulations that are geared specifically towards smokeless tobacco. For example, the Act includes a provision that limits the distribution of free samples of smokeless tobacco products to "adult-only facilities," the FDA having found that free samples otherwise constitute a "risk-free and cost-free way for young people to obtain and possibly use cigarettes or smokeless tobacco." FSPTCA Report at 47; 21 U.S.C. § 387a-1(a)(2)(G). The Act also provides the FDA with the authority (following rulemaking) to revise the labeling requirements for smokeless tobacco. FSPTCA Report at 39-40. And the Act prohibits the sale and distribution of smokeless tobacco as a "modified risk tobacco product"—that is, smokeless tobacco may not be advertised or sold "for use to reduce harm or the risk of tobacco-related disease." FSPTCA Report at 90; 21 U.S.C. § 387k(b)(2)(C).

In addition to the regulations contained in the Act, the Act grants the FDA the power to "***revise*** the tobacco product standards" contained in Section 907 of the Act, including the "Special Rule for Cigarettes," as long as the FDA complies with certain rulemaking procedures specified in the Act. 21 U.S.C. § 387g(a)(2) (emphasis added). The Act also confers discretion on the FDA to ***adopt additional*** tobacco product standards—including standards that would apply to smokeless tobacco—provided that

the FDA first makes a finding that any such new standard is "appropriate for the protection of public health." 21 U.S.C. § 387g(a)(3).

The FDA has not yet made any such finding or issued any product standard relating to smokeless tobacco products.

B. State and Local Authority Under the FSPTCA

With regard to federal-state relations, Section 916 of the Act, entitled "Preservation of State and Local Authority," contains three clauses that address the power of state and local governments to enact laws relating to tobacco products: a preemption clause, a saving clause and a preservation clause. These clauses create the balance of power between the state and federal governments, and must be considered in light of the following congressional findings, which appear to recognize a parallel role for the states in regulating tobacco products:

- "Federal *and State* public health officials, the public health community, and the public at large recognize that the tobacco industry should be subject to ongoing oversight."
- "Federal ***and State*** governments have [historically] lacked the legal and regulatory authority and resources they need to address comprehensively the public health and societal problems caused by the use of tobacco products."
- "Because past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, ***comprehensive restrictions on the sale, promotion, and distribution of such products are needed.***"

Pub. L. No. 111-31, Div. A, § 2 (Findings), 123 Stat. 1776, 1777 (2009) (emphasis added); see also 21 U.S.C. § 387 (Findings (6)-(8)).

1. The Preservation Clause

The preservation clause, codified at 21 U.S.C. § 387p(a)(1), precedes the Act's preemption and saving clauses structurally. It states that:

> nothing in this subchapter, or rules promulgated under this subchapter, shall be construed to limit the authority of a Federal agency (including the Armed Forces), a State or political subdivision of a State, or the government of an Indian tribe to enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that is in addition to, or more stringent than, requirements established under this subchapter, including a law, rule, regulation, or other measure relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products.

Id.

The Act's preservation clause makes it clear that state and local governments can make an additional (and stronger) "law, rule, regulation, or other measure" "with respect to" "tobacco products," other than the law passed by Congress or the regulations promulgated by the FDA, including laws that "prohibit the sale [or] distribution . . . of tobacco products."[2] See id.

The fact that the preservation clause focuses on how provisions of the Act should be "construed" suggests that the purpose of the clause is to establish a presumption

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[2] The preservation clause is, like so many congressional enactments, awkwardly worded. By not placing a comma between the words "use of" and "tobacco products by individuals of any age," Congress, as a grammatical matter, untethered all of the preceding antecedents ("sale, distribution, possession, exposure to, access to, advertising and promotion of") from the words "tobacco products." The rule of the last antecedent provides that a limiting clause or phrase should ***ordinarily*** be read as modifying only the noun or phrase that it immediately follows. See In re Enron Creditors Recovery Corp. (Alfa S.A.B. de C.V. v. Enron Creditors Recovery Corp.), 422 B.R. 423, 433 (S.D.N.Y. 2009); In re Enron Creditors Recovery Corp. (J.P. Morgan Chase Bank N.A. v. Baupost), 380 B.R. 307, 319-22 (S.D.N.Y. 2008); see also Barnhart v. Thomas, 540 U.S. 20, 26-28 (2003) (Scalia, J.). But in passing the FSPTCA, Congress obviously did not intend to legislate with respect to any products other than tobacco products, so it makes no sense to read the preservation clause in accordance with the rule of the last antecedent. Otherwise, the preservation clause would direct courts not to construe the FSPTCA to prohibit state and local regulation of the sale or distribution of anything and everything. That is a nonsensical way to read the law. I therefore decline to read the preservation clause per the rule of the last antecedent.

against field (or implied) preemption—that is, the preservation clause advises courts and state and local authorities that the Act was intended to have a ***limited*** preemptive scope.

2. The Preemption Clause

The preservation clause is followed by Section 916's preemption clause, codified at 21 U.S.C. § 387p(a)(2)(A), which provides:

> No state or political subdivision of a State may establish or continue in effect with respect to a tobacco product any requirement which is different from, or in addition to, any requirement under the provisions of this subchapter relating to ***tobacco product standards,*** premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

Id. (emphasis added).

The preemption clause restricts the power of state and local governments to adopt, among other things, their own "tobacco product standards," which are "different from, or in addition to" federal tobacco product standards. Read literally, and absent any additional statutory context, the Act's preemption clause suggests that Congress intended the FSPTCA to preempt "different" or "additional" state "requirements" "relating to" "tobacco product standards," 21 U.S.C. § 387p(a)(2)(A), including "restrictions" on "the sale and distribution of the tobacco products," 21 U.S.C. § 387g(a)(4)(B)(v) (listing tobacco product standards). Pursuant to Section 906(d), that could include "restrictions on the access to, and the advertising and promotion of, the tobacco product," 21 U.S.C. § 387f(d)(1), since the term "tobacco product standard" includes such provisions.

3. The Saving Clause

However, the preemption clause is followed by Section 916's saving clause, codified at 21 U.S.C. § 387p(a)(2)(B), which the Act identifies as an "exception" to the Act's express preemption provisions. The saving clause states that the preemption clause

> does *not* apply to ***requirements relating to the sale, distribution . . . advertising andpromotion of . . . tobacco products by individuals of any age.***

21 U.S.C. § 387p(a)(2)(B) (emphasis added).

The saving clause incorporates (in a slightly rearranged order) the language from the preservation clause about the types of regulations that state and local governments are allowed to pass—including restrictions on the sale or distribution of tobacco products.

II. New York City's Flavored Tobacco Ordinance

On October 28,2009, New York City Mayor Michael Bloomberg signed the City's flavored tobacco ordinance into law. See N.Y. City Admin. Code. §§ 17-713-718 (the "Ordinance" or "City Ordinance"). The City Ordinance makes it "unlawful for any person to sell or offer for sale any flavored tobacco product except in a tobacco bar." N.Y. City Admin. Code § 17-715. The Ordinance applies only to "flavored tobacco products," defined as "any tobacco product or any component thereof that contains a constituent that imparts a characterizing flavor." N.Y. City Admin. Code § 17-713(e). A "characterizing flavor" is "a distinguishable taste or aroma, other than the taste or aroma of . . . a tobacco product or component part thereof, including, but not limited to, tastes or aromas relating to any fruit, chocolate, vanilla, honey, candy, cocoa, dessert, alcoholic beverage, herb or spice." N.Y. City Admin. Code § 17-713(b). And a "tobacco product" is "any substance which contains tobacco, including, but not limited to, cigars and chewing tobacco; provided, however, that ***such term shall not include cigarettes.***" N.Y. City Admin. Code § 17-713(j) (emphasis added). Thus, while the FSPTCA includes an explicit ban on the manufacture of flavored cigarettes, the City's Ordinance does not reach that product. It restricts only the sale of flavored tobacco products other than

cigarettes. Neither Congress nor the FDA has imposed any sales restriction on such products.

A "tobacco bar" is defined as a "bar that, in the calendar year ending December 31,2001, generated ten percent or more of its total annual gross income from the on-site sale of tobacco products and the rental of on-site humidors, not including any sales from vending machines, and is registered with the department of health and mental hygiene in accordance with the rules of such agency." N.Y. City Admin. Code § 17-502(jj) (defining tobacco bar). The Ordinance defines "person" as "any natural person, partnership, firm, joint stock company, corporation, or employee thereof, or other legal entity." N.Y. City Admin. Code § 17-713(g). Plaintiffs explain that the City "does not appear to publish" information regarding the number of tobacco bars citywide, but "as of 2005 there were fewer than ten such tobacco bars." (Pls. Br. in Supp. of Prelim. Inj. ("Pls. Br"), Jan. 26, 2010, at 4) (citing Tom Acitelli, "Cigar Bars Spark Profits," The Real Deal (Nov. 1, 2005)).) Plaintiffs further aver that tobacco bars account for only 1.21% of the venues in which flavored smokeless tobacco products were sold during 2009. They argue that the City's Ordinance operates as a de facto ban on the sale of flavored tobacco. (Id. at 4-5, 17.)

The New York City Departments of Health and Consumer Affairs are tasked with enforcement of the City's Ordinance. N.Y. City Admin. Code § 17-717. The penalty for a first violation is a fine of "not more than five hundred dollars" for each violation found on that day. N.Y. City Admin. Code § 17-716(b). A second violation within two years carries a fine of not more than one thousand dollars per violation, while a third violation carries a fine of not more than two thousand dollars per violation. A retailer's third

violation also results in the mandatory suspension of its cigarette license for up to one year. Id. The language of the Ordinance does not appear to limit penalties for violations to retailers.

New York City's Ordinance was originally scheduled to go into effect on or about February 25,2010; however, the City has informed the Court that it will not enforce the new law until it completes its rulemaking process. This postpones the effective date for the legislation until April or sometime shortly thereafter. (Letter from S. Kurland to the Court (Feb. 10, 2010).)

111. The Ordinance's Impact on Plaintiffs' Business

Plaintiff U.S. Smokeless Tobacco Manufacturing Company LLC ("Smokeless Tobacco Mfg.") manufactures Copenhagen, Skoal, Red Seal and Husky brands of smokeless tobacco, some of which plaintiffs believe are "flavored smokeless tobacco" products within the meaning of the Ordinance. (Compl. ¶ 13; Pls. Br. at 5.)

Plaintiff U.S. Smokeless Tobacco Brands, Inc. ("Smokeless Tobacco Brands") purchases smokeless tobacco from Smokeless Tobacco Mfg., including products that plaintiffs believe may be "flavored tobacco products" within the meaning of the Ordinance. (Id.) Smokeless Tobacco Brands then resells these tobacco products to distributors located in New York City and elsewhere. (Id.) Those distributors sell smokeless tobacco products to retailers located in New York. (Id.)

Plaintiffs aver that if Smokeless Tobacco Mfg. and Smokeless Tobacco Brands are forced to comply with the Ordinance, they will have to alter "their production, distribution, and marketing procedures. In addition, they will lose revenue, brand equity, adult tobacco consumers, and market share." (Id. at 6 (citations omitted).)

DISCUSSION

I. Preliminary Injunctive Relief

Generally, a party seeking a preliminary injunction must demonstrate that it will suffer irreparable harm absent injunctive relief, and either (1) that it is likely to succeed on the merits of the action; or (2) that there are sufficiently serious questions going to the merits to make them fair ground for litigation, provided that the balance of hardships tips decidedly in favor of the moving party. Citigroup Global Mkts.. Inc. v. VCG Special Opportunities Master Fund Ltd., No. 08 Civ. 6090,2010 WL 786584, at *3 (2d. Cir. Mar. 10,2010) (citation omitted). When a party seeks an injunction that will affect governmental action taken in the public interest, the plaintiff must show a threat of irreparable harm and a likelihood of success on the merits—a serious question going to the merits is not enough, even if the balance of hardships tips decidedly in the applicant's favor. Monserrate v. New York State Senate, No. 10 Civ. 0604,2010 WL 917591, at *3 (2d Cir. Mar. 16,2010) (citation omitted).

A preliminary injunction "is not a remedy which issues as of course." Weinberaer v. Romero-Barcelo, 456 U.S. 305,311 (1982) (quoting Harrisonville v. W. S. Dickey Clay Mfg. Co., 289 U.S. 334, 337-38 (1933)). Rather, a preliminary injunction is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." Winter v. NRDC, Inc., 129 S. Ct. 365,375-76 (2008).

A. Likelihood of Success on the Merits

The gravamen of plaintiffs' argument is that the FSPTCA preempts the City's Ordinance because the Ordinance purports to establish a "tobacco product standard" by placing restrictions on the sale of flavored tobacco—a restriction based upon the

product's constituent properties. Plaintiffs contend that the FSPTCA's preemption clause expressly reserves such power to the FDA. As explained below, plaintiffs' gloss on the FSPTCA overlooks several of the Act's key provisions, the lack of an actual conflict between the federal and local law, and the judicial presumption against preemption in matters of health and safety. Therefore, the Court finds it highly unlikely that plaintiffs will ultimately prevail on the merits, and their motion for a preliminary injunction is denied.

1. The Plain Language of the FSPTCA

As with any question of statutory interpretation, a court's analysis begins with the plain language of the statute. Lamie v. United States Trustee, 540 U.S. 526, 534 (2004). It is well-established that when the statutory language is plain, it must be enforced according to its terms. See, e.g., Dodd v. United States, 545 U.S. 353, 359 (2005); Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A., 530 U.S. 1, 6 (2000); Caminetti v. United States, 242 U.S. 470,485 (1917). "The preeminent canon of statutory interpretation requires us to 'presume that [the] legislature says in a statute what it means and means in a statute what it says there.'" BedRoc Ltd., LLC v. United States, 541 U.S. 176, 183 (2004) (citing Connecticut Nat. Bank v. Germaine, 503 U.S. 249, 253-54 (1992)). The plain language of the FSPTCA evidences no intent to preempt a local ordinance restricting the sale of flavored tobacco. Indeed, the language of the FSPTCA supports New York's authority to enact such a law.

The Act's preservation clause explicitly provides that no part of the Act "shall be construed to limit the authority" of a local government to "enact, adopt, promulgate, and enforce any law, rule, regulation, or other measure with respect to tobacco products that

is ***in addition to, or more stringent than,*** requirements established under this subchapter, ***including*** a law, rule, regulation or other measure ***relating to or prohibiting the sale [or] distribution*** . . . of tobacco products." 21 U.S.C. § 387p(a)(1) (emphasis added). The preservation clause plainly contemplates local regulations restricting and/or banning the sale of subclasses of tobacco products (such as flavored tobacco products)—it explicitly refers broadly to all "tobacco products." This is true notwithstanding the fact that the FDA has been vested with discretion to regulate the sale of tobacco products "sold through means other than a direct, face-to-face exchange," FSPTCA Report at 37; see also 21 U.S.C. §§ 387f(d)(1)&(3)(A), and that the agency "may by regulation require restrictions on the sale and distribution of a tobacco product, including restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary determines that such regulation would be appropriate for the protection of the public health," 21 U.S.C. § 387f(d)(1). Thus, the preservation clause instructs this Court not to interpret any of the Act's provisions as preventing a city from "prohibiting" (or otherwise restricting) the "sale" of tobacco products. See 21 U.S.C. § 387p(a)(1) (preservation clause), even though the FDA ***could*** regulate the "sale" of such products at some future date.

Additionally, the saving clause, which is identified in the FSPTCA as an "exception" to preemption, states in relevant part that the preemption clause "does ***not*** apply to [state or local] requirements relating to the ***sale [or] distribution*** . . . ***of tobacco products.***" 21 U.S.C. § 387p(a)(2)(B) (emphasis added). Carving out an exception to federal preemption for local ordinances relating to the sale or distribution of tobacco products makes perfect sense. While the FDA is authorized to restrict the sale or

distribution of tobacco products if it finds that such a restriction is in the public interest—and while any such restriction could fall under the rubric "tobacco product standards"[v]—it seems clear that the primary purpose of the "tobacco product standards" is to regulate the manufacture of tobacco products. Nearly all of the "tobacco product standards" mentioned in the FSPTCA relate to the content of tobacco products: they regulate nicotine yields, 21 U.S.C. § 387g(a)(4)(A)(i); require the reduction or elimination of other tobacco constituents, 21 U.S.C. § 387g(a)(4)(A)(ii); relate to the construction, components, ingredients, additives, constituents, and properties of the tobacco product, 21 U.S.C. § 387g(a)(4)(B)(i); provide for the testing of the contents of tobacco, 21 U.S.C. § 387g(a)(4)(B)(ii); provide for the measuring of tobacco characteristics, 21 U.S.C. § 387g(a)(4)(B)(iii); and require foreign-grown tobacco to meet the same standards as domestic tobacco, 21 U.S.C. § 387g(a)(4)(D). Each of these standards relates clearly and directly to the fabrication of tobacco products—an area in which uniform regulation is not only advisable but necessary.

Plaintiffs say that the City Ordinance is effectively regulating the manufacture of tobacco by restricting the point of purchase for flavored tobacco to tobacco bars, since the City Ordinance relates to a subclass of tobacco products identified by their contents (i.e., a characterizing flavor). It is undisputed that the City Ordinance does nor refer to the fabrication or manufacture of such products; it limits only the sale of flavored tobacco products other than cigarettes. It is also undisputed that the FSPTCA's tobacco product standards contain no regulations regarding the manufacture of flavored tobacco products other than flavored cigarettes, and that the FSPTCA grants states and localities the power to regulate sales—without qualification. By explicitly "preserving" and "saving" the

right of state and local governments to regulate the sale and distribution more (but not less) restrictively than the FDA might, Congress expressed a clear and unmistakable preference for limiting the federal government's role to setting a floor below which no local sales regulations could go, while remaining sensitive to differing sensibilities about the use of tobacco products in different parts of the country.

Plaintiffs argue that the saving clause does not exempt all locally-imposed requirements relating to the sale and distribution of tobacco products from the preemption clause, but only age-related requirements, like those that require "the presentation of identification prior to any purchase, the presentation of identification only by persons who appear to the retailer to fall under a particular age, and/or the presentation of identification of a particular type, e.g., only certain forms of government-issued identification." (Pls. Br. at 17.) No such language appears in the clause itself. As noted above, the clause exempts from preemption any local requirements "relating to the sale, distribution, possession, information reporting to the State, exposure to, access to, the advertising and promotion of, or use of, tobacco products by individuals of any age." Under the familiar rule of the last antecedent, ***see supra*** n.2, the presence of that last comma—the one before the words "tobacco products by individuals of any age'—means that the phrase "tobacco products by individuals of any age" is modified by every item in the list of nouns that precedes it. That is, the saving clause carves out all of the following local regulations from federal preemption:

- the sale [of] tobacco products by individuals of any age;
- the distribution [of] tobacco products by individuals of any age;
- the possession [of] tobacco products by individuals of any age;

- information reporting to the State by individuals of any age;
- exposure to tobacco products by individuals of any age;
- access to tobacco products by individuals of any age
- the advertising and promotion of tobacco products by individuals of any age;
- use of tobacco products by individuals of any age.

None of these phrases suggests that the saving clause was intended to apply, or should be read to apply, only to requirements based on the age of purchasers of tobacco products. Indeed, read literally, the saving clause does not relate to the sale or distribution of tobacco products *to* anyone at all—only by anyone—and that "anyone" can be a person of any age.[3] The reference to "individuals of ***any*** age" in the statute cannot plausibly be read as a requiring all restrictions relating to the sale of tobacco products to be based on the age of the consumer. The saving clause contains a blanket exception for locally-imposed requirements "relating to," inter alia, the sale and distribution of tobacco products—regardless of the age of the individual to whom any restriction on sale or distribution applies.

Even if the saving clause could be read in the manner suggested by the plaintiffs, the reading urged by the City and adopted by this Court—which rests on the literal words of the statute—is at least as plausible as the reading expounded by plaintiffs. And "where

[3] As I noted above, the analogous language in the preservation clause, which preserves the right of states and localities to make additional and more stringent rules "relating to or prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age" does not include the last comma. Unfortunately, inserting the punctuation, while solving the last antecedent" problem, creates its own issues. Clearly, the preposition "by" ought to read "to" in at least some of the above instances ("sale of tobacco products *to* individuals of any age," for example). And the placement of the comma after the word "of," rather than before it, creates yet another textual problem. However, these grammatical issues do not make plaintiffs' reading of the saving clause plausible.

the text of a preemption clause is ambiguous or open to more than one plausible reading, courts have a duty to accept the reading that disfavors pre-emption." New York State Restaurant Ass'n v. New York City Bd. of Health, 556 F.3d 114, 123 (2d Cir. 1999) (internal quotations omitted); accord Bates v. Dow Agrosciences LLC, 544 U.S. 431,449 (2005).

2. The Ordinance Does Not Conflict with the FSPTCA

Having concluded that the plain language of the statute supports the City's authority to enact its law, the Court turns to an implied conflict preemption analysis, which is informed by two basic precepts. First, state action is not ordinarily pre-empted just because it imposes some requirement over and above that of a federal law. See California v. ARC America Corp., 490 U.S. 93, 105 (1989) (citing Silkwood v. Kerr-McGee Corp., 464 U.S. 238,257-58 (1984); California v. Zook, 336 U.S. 725,736 (1949)). Second, there is a presumption against preemption in cases where, as here, the federal government has legislated in a field traditionally left to the discretion of the states. English, 496 U.S. at 89. As the Supreme Court recognized in Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724 (1985), "states traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all person." Id. at 756 (internal quotations omitted). Therefore, absent an actual conflict with a federal statute, preemption of a local law would be wholly inappropriate.

There is no conflict here. Both the federal and the City law apply to some of the same products. Compare, e.g., 21 U.S.C. § 321(rr)(1)-(2) (defining tobacco product to include smokeless tobacco) and N.Y. City Admin. Code § 17-713(j) (same). However,

the only restriction the FSPTCA affirmatively places on flavored tobacco products relates to flavored cigarettes, see 21 U.S.C. § 387g(a)(1)(A), and the City Ordinance explicitly states that it does ***not*** apply to cigarettes, see N.Y. City Admin. Code § 17-713(j). Moreover, because the City Ordinance does not apply to cigarettes, it does not conflict with Congress' finding that a ban on tobacco or menthol cigarettes could lead to "negative health effects," because they are products "used regularly by a large number of addicted adult smokers." FSPTCA Report at 38. At most, the City Ordinance applies sales restrictions on flavored tobacco products (by limiting where they may be purchased) over and above those imposed by the federal law. For the reasons explained above, that is not a valid basis for finding preemption in this case. See California v. ARC America Corp., 490 U.S. 93,105 (1989) (citing Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 257-58 (1984); California v. Zook, 336 U.S. 725, 736 (1949)).

The fact that the FSPTCA provides that the FDA may, at some future date, promulgate regulations restricting the sale of flavored tobacco products other than cigarettes is not enough—in and of itself—to impute a conflict between federal and city law. As the Supreme Court has explained, there is a difference between (i) an affirmative restriction contained on the face of a statute, and (ii) a statutory scheme, like the one at issue here, that depends upon the issuance of agency regulations. See Medtronic v. Lohr, 518 U.S. 470,496 (1996).

In Lohr, the Supreme Court declined to expansively interpret an analogous preemption provision of the Medical Device Amendments ("MDA"), in part because under that statute, the "specifics" of the "territory exclusively occupied by federal law" did not "exist ***until*** the FDA provide[d] them," Lohr, 518 U.S. at 489 n.9 (plurality

opinion of Stevens, J.) (emphasis added), and in certain areas, the FDA had provided no such specifics, id. at 492-94 (majority opinion). In so holding, the Supreme Court distinguished its previous decision in Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992), where the Court had interpreted apreemption provision broadly. Lohr, 518 U.S. at 496. Specifically, the Court explained that "[u]nlike the statute construed in Cipollone . . . pre-emption under the MDA does not arise directly as a result of the enactment of the statute; rather, in most cases a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.'" Id.; accord id. at 489 n.9 (noting that "the precise warning that Congress deemed both necessary and sufficient" was contained on the face of the statute itself in Cipollone). Unlike the provisions at issue in both Lohr and this case, the preemption provision at issue in Cipollone did not rely for its force on regulations that might be promulgated by a federal agency at some future date.

The (admittedly limited) legislative history of the Act's preemption provisions also supports a narrow reading of the preemption clause. The FSPTCA Report accompanying the bill explains, the Act's preemption clause applies only in "specific and ***limited*** areas." FSPTCA Report at 45 (emphasis added). Further, as Rep. Foxx explained in her testimony, the FSPTCA actually rolls back the preemption provisions of another federal law regulating tobacco products—the Federal Cigarette Labeling and Advertising Act (the "FCLAA"). Referring to the advertising provisions of the FSPTCA, Rep. Foxx stated: "It [the FSPTCA] would provide only ***limited*** pre-emption of state laws, allowing more rigid ***state restrictions*** on tobacco advertising." 155 Cong. Rec. H6630-01, H6659, 2009 WL 1643915 (daily ed. June 12, 2009) (statement of Rep. Foxx) (emphasis added). Representative Foxx's testimony is especially significant because it addresses a key area

of overlap between state and federal regulation under the FSPTCA — advertising; tobacco product standards can include restrictions on advertising, which are considered to be a subspecies of sale and distribution under Section 906(d) of the FSPTCA. See 21 U.S.C. § 387g(a)(4)(B)(v) (tobacco product standards, referencing Section 906(d), 21 U.S.C. § 387d); 21 U.S.C. § 387f(d)(1) (Section 906(d), sale and distribution includes restrictions on advertising). Her testimony makes clear that Congress contemplated a role for the states in regulating tobacco products.

Moreover, the advertising context may partially elucidate Congress' intention in incorporating references to age in the preservation and saving clauses. The Supreme Court interpreted the preemptive scope of the FCLAA's advertising provisions in the context of a state law targeted at reducing the incidence of smoking among minors. See Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001). That law, passed by the Massachusetts legislature, prohibited outdoor cigarette advertising within 1,000 feet of a school or playground and prohibited the posting of cigarette advertisements in stores at less than five feet from the ground (so as to ensure that cigarette ads were not a children's eye level). Id. at 535 (citation omitted). In Lorillard, the Supreme Court held that the law was preempted by the FCLAA. The FSPTCA was passed in part to amend the FCLAA's advertising provisions, by adopting restrictions that are nearly-identical to the Massachusetts ban at issue in Lorillard. See Commonwealth Brands Inc. v. United States, No. 09 Civ. 117,2010 WL 65013, at *16 (W.D. Ky. Jan. 14, 2010) (comparing the FSPTCA to the law at issue in Lorillard). The fact that the law at issue in Lorillard was solely targeted at preventing smoking by minors suggests that the FSPTCA's reference to "individuals of any age" was Congress' way of saying that the carve-outs for

state prerogative would not be limited to enacting laws aimed only at minors—especially since the FSPTCA explicitly "preserves" and "saves" the powers of the states to enact restrictions on tobacco advertising. See 21 U.S.C. § 387p(a)(1) (preservation clause); id. § 387p(a)(2)(B) (saving clause).

It is of no moment that neither the FSPTCA nor anything in its legislative history affirmatively provides that "state and local governments may enact restrictions on the sale of flavored tobacco, notwithstanding the provisions of this Act." The City has done no more than the plain language of the preservation and saving clauses allow, and as explained above, there is no basis on which to find that the City Ordinance is not "consistent with the structure and purpose" of the Federal statutory scheme, Gade v. National Solid Wastes Management Ass'n, 505 U.S. 88, 98 (1992) (plurality opinion of O'Connor, J.); Lohr, 518 U.S. at 486 (citations omitted). The Court, therefore, denies plaintiffs' motion for a preliminary injunction.

Because plaintiffs have failed to discharge the "heavy burden" of demonstrating that they are likely to succeed on the merits of their claims, see New York v. Nuclear Regulatory Comm'n, 550 F.2d 745,750 (2d Cir. 1977), the Court does not reach the question of whether plaintiffs have established irreparable injury.

CONCLUSION

Plaintiffs' motion for a preliminary injunction (docket no. **7)** is denied. The Clerk of the Court is instructed to remove the motion at docket no. **7** from the Court's outstanding motion list.

Dated: March 22,2010

U.S.D.J.

BY ECF AND EMAIL TO ALL PARTIES